**Category** : Study conduct
**Title** : Birth control measures- women participants.
**SOP No.** : D 09/06
**Date first effective:** 01 Jan 2024 **Review date:** 31 Dec 2024

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## 1. Purpose

The purpose of this standard operating procedure (SOP) is to describe the responsibilities of the research team towards counseling of women participants regarding the birth control measures to be adopted during the study period and the procedures to be followed in case a participant is diagnosed to be pregnant during the study period.

## 2. Scope

This SOP is applicable to all women in reproductive age group who are likely to participate in a clinical trial.

## 3. Responsibilities

Principal investigator (PI), Co-investigator (Co-I), Study Coordinator or any other appropriately qualified staff in the team, as delegated by the Principal Investigator, will be responsible for counseling of women participants regarding the birth control measures to be adopted during the study period.

## 4. Applicable rules, regulations and guidelines

- New Drugs and Clinical Trials Rules, 2019 https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf (last accessed 20th Dec, 2023)
- Ethical Guidelines for Biomedical and Health Research involving Human Participants, ICMR 2017 http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf (last accessed 20 Dec 2023)
- ICH-GCP E6 (R3) Draft Guidelines dated 19th May 2023 https://database.ich.org/sites/default/files/ICH_E6%28R3%29_DraftGuideline_2023_0519.pdf

## 5. Reference to other applicable SOPs

SOP No D 03/06: Responsibilities of the Study Team

SOP No D 15/06: SAE documentation and reporting

## 6. Detailed instructions

1. During the screening visit, record and document a detailed medical, gynecological and obstetric history of the female participant.
2. Ask the participant regarding use of any birth control measures, present and past; both by self and her spouse.
3. If yes, document the type of birth control measures used and advise the participant to continue the same, if the method of contraception is permitted as per the protocol.
4. If not, assess the willingness of the participant to adopt birth control measures recommended in the protocol and offer the available options to the participants e.g. condoms for the male partner and/or oral contraceptives/barrier contraception/intra uterine device (if the protocol permits) to the participant following consultation with a Gynecologist.
5. Gynecology consultation should be sought with the relevant OPD of KEM Hospital as decided by the PI.
6. If the participant is not willing to adopt birth control measures and this is necessary as per the protocol, then she cannot be recruited into the study.
7. It is necessary to emphasize the risk of pregnancy while in the study and its consequences (in the absence of adequate birth control measures).
8. Explain to the participant that a serum and/or urine pregnancy test will be performed at the screening visit and any subsequent visit as per protocol requirements.
9. Ensure that the participant understands the importance about reporting to the study physician in case she misses her menstrual period. In such cases, she should be advised to undergo a pregnancy test and ultrasonography.

10. If pregnancy is confirmed during the trial/study period, refer the participant to the obstetrician of the institute and document and report the same as serious adverse event (SAE) (See SOP D 15/06) and follow the mother throughout the pregnancy period till delivery to monitor the mother's and baby's health status.
11. If the woman is not pregnant, then re-emphasize the importance of preventing a pregnancy during the study period and use of a birth control measure.
12. Always follow the instructions in the protocol regarding withdrawal from the study.

## 7. Abbreviations:

i. **AE**: Adverse Event
ii. **Co-I:** Co-investigator
iii. **OPD:** Out Patient Department
iv. **PI:** Principal investigator
v. **SAE:** Serious Adverse Event
vi. **SOP:** Standard Operating Procedure

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